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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,635	03/16/2001	Martin Gerber	9793/035 BMID 9977	7384
23690	7590	05/13/2004	EXAMINER	
Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			ROBINSON, DANIEL LEON	
			ART UNIT	PAPER NUMBER
			3742	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/810,635	GERBER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel I. Robinson	3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-64 and 78-82 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,19,20 and 26 is/are rejected.
- 7) ☒ Claim(s) 2,9-11,13-18,21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-30-2001 3-7-2003</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4-8, 19, 20, 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al.(U.S.Pat.6,654,620) in view of Van Antwerp et al.(U.S.Pat.6,011,984). Wu discloses a method and apparatus for improving non-invasive determination of the concentration of analytes in a biological sample that shows many of the features of the claimed invention but fails to show a membrane. Van Antwerp discloses a detection method and apparatus of biological molecules using chemical amplification and optical sensors that explicitly shows using a membrane. It would have been obvious to one of ordinary skill at the time of the claimed invention to use a membrane as taught by Van Antwerp with the device of Wu so as to limit the glucose concentration and the analytical signal.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in View of Van Antwerp as applied to claims 1, 3, 4-8, 19, 20 and 26 above, and further in view of Simons(U.S.Pat.5,227,040). Wu in view of Van Antwerp does not show a membrane comprised of a bipolar cation and anion exchange layers. Simons discloses a high performance bipolar membrane that explicitly shows a bipolar membrane. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention

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to use a bipolar membrane as taught by Simons with the device of Wu in view of Van Antwerp so the electrical resistance would be lowered.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in View of Van Antwerp as applied to claims 1, 3, 4-8, 19, 20 and 26 above, and further in view of Shemwell et al.(U.S.Pat.6,095,974) and Steffes(U.S.Pat.6,442,410). Wu in view of Van Antwerp does not explicitly show a readout driven by an electrical signal. Steffes disclose a blood glucose measurement system and method using optical refractometry that shows using a readout and Shemwell discloses a disposable fiber optic probe that shows a transducer that converts a two input coupler output via a transducer to an electrical signal. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to convert the output of the coupler to an electrical signal, as taught by Shemwell, so as to drive the readout display of Steffes.

Claims 27, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in View of Van Antwerp as applied to claims 1, 3, 4-8, 19, 20 and 26 above, and further in view of Yamashita et al.(U.S.Pat.6,611,698). Wu in view of Van Antwerp does not show light emitting diode or a photodiode detector. Yamashita discloses an optical instrument that shows using a diode detector and a light emitting diode. It would have been to one of ordinary skill in the art at the time of the claimed invention to a light emitting diode that is highly reliable and a photodiode detector because it is highly sensitive to light.

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*Allowable Subject Matter*

Claims 2, 13-18, 21, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

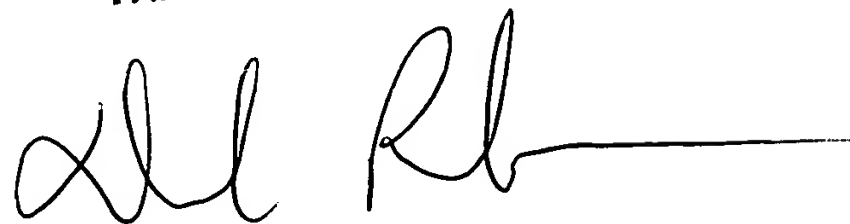
Claims 53-64 and 78-82 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel I. Robinson whose telephone number is 703 306-9043. The examiner can normally be reached on M-F 5:30am-2:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**DANIEL ROBINSON**  
**PATENT EXAMINER**

A handwritten signature in black ink, appearing to read 'D. I. Robinson', followed by a horizontal line extending to the right.